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10/029,559	12/20/2001	Michael V. Chobotov	24641-7005	4960
20350	7590	06/23/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP			PREBILIC, PAUL B	
TWO EMBARCADERO CENTER			ART UNIT	
EIGHTH FLOOR			PAPER NUMBER	
SAN FRANCISCO, CA 94111-3834			3738	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,559

Applicant(s)

CHOBOTOV ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 124-126, 131-133, 135-139, 141 and 142 is/are allowed.
- 6) ☒ Claim(s) 72-123, 127, 134 and 140 is/are rejected.
- 7) ☒ Claim(s) 128-130 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/9/04 + 4/504.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Specification

The disclosure is objected to because of the following informalities:

On page 1, lines 4-14, the continuing data is not restricted to related cases (e.g. continuation, continuation-in-part, or divisional applications), and therefore, it is not proper for a statement of related cases. By "related" applications, the USPTO means one of continuation, continuation-in-part, or divisional applications. For this reason, it is improper to list similar applications under the heading "related" applications.

In addition, the continuing data on page 1 has three blank spaces for serial numbers such that it is incomplete.

Furthermore, the continuing data may need to be updated with the current status of any related cases; e.g. patent number or abandoned status.

There is no label of "Detail A" (Figure 5) in the figures even though it is referred to in the specification; see page 5, line 3.

Appropriate correction is required.

The amendment filed April 5, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

The amendment filed April 5, 2004 inserts serial numbers into the specification. However, since the original specification did not contain any other information on these particular applications (i.e. title, attorney docket number,

Art Unit: 3738

filing date, etc.), entry of these serial numbers adds new matter to the original specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

In response to the Applicants' traversal that the applications listed on page 1 of the specification are related but not continuing applications, the Examiner asserts that by the terminology "related" applications, the USPTO means one of continuation, continuation-in-part, or divisional applications. For this reason, it is improper to list similar applications under the heading "related" applications.

In response to the Applicants' statement that the blank lines on page 1 of the specification were filed by the amendment of June 14, 2002, the Examiner has reviewed that amendment and found no such amendment. However, it does appear that page 1 of that amendment is missing. Therefore, in response to this Office action, Applicants are respectfully requested to provide the missing information as long as it does not introduce new matter into the specification and is proper for being under the heading for "related" applications.

Claim Objections

Claims 83, 85, 135, 136, 141, and 142 are objected to because of the following informalities:

Regarding claim 83, line 2, "is projects" is grammatically awkward.

Art Unit: 3738

Regarding claim 85, line 1, "the barbs" lacks antecedent basis from claim 74.

Regarding claims 135, 136, 141, and 142, "the one or more barbs" lacks clear antecedent basis. Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed February 9, 2004 was not fully considered because a legible copy of each U.S. and foreign patent could not be found; only 2 of apparently a total of 4 boxes could located after a thorough search. Therefore, the Examiner could only consider the references that were initialed on the enclosed PTO-1449. The Office regrets any inconvenience that this may cause Applicants, but Applicants are respectfully requested to provide replacement copies of the missing documents. Moreover, the Examiner requests that the missing documents be provided in the form of an eIDS statement so that the documents can be more easily accessed and reviewed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 81, 82, 84, 89, 127, 134 and 140 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

Art Unit: 3738

possession of the claimed invention. The Examiner could not find original support for the subject matter of these claims. Therefore, the Examiner asserts that these claims contain new matter. If Applicants believe that there is support for the claimed subject matter, they are asked to point out the particular page and line number or drawing figure number that provides support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72, 73, 80, 86-90, 94, 96, 99 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanesaka et al (US 5,911,754). Kanesaka anticipates the claim language where the first portion as claimed is met by the small mesh portion (3) of Kanesaka which has 8 apices, the second portion as claimed is met by the large mesh portion (2) of Kanesaka which has 4 apices, and the connectors as claimed are met by the connectors (5) of Kanesaka; see Figure 1 and column 3, lines 14-57.

With regard to claim 86 specifically, the diameter would inherently vary somewhat because of manufacturing imperfections. Furthermore, the diameter would vary depending upon how the stent was expanded which could be done in segments.

Art Unit: 3738

Claims 102, 103, 106-108, 111-115, and 122-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Marin (US 5,397,355). Marin anticipates the claim language where the barbs as claimed are the barb (18) of Marin, and the tuck pads as claimed are the collinear barbs (16) and ribs (14) that hold and conceal the barb prior to deployment; see the figures and column 2, line 20 to column 3, line 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 74, 75, 78, 79, 83-85, 92 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka et al (US 5,911,754) in view of Goicoechea et al (US 5,800,508).

With regard to claims 74, 75, 78, 79, 83-85, 92 and 93, Kanesaka meets the claim language as explained above but fails to disclose the use of barbs thereon. However, Goicoechea teaches that it was known to put barbs on similar stents to help in the anchoring of the stent and to prevent migration; see the abstract. Therefore, it is the Examiner's position that it would have been prima facie obvious to put barbs on the Kanesaka device for the same reasons as Goicoechea.

Art Unit: 3738

With regard to claims 78 and 79, Kanesaka as modified by Goicoechea fails to teach the claimed size range. However, the mere recitation of a size does not in itself render an unpatentable device patentable; see MPEP 2144.04

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claims 83 and 84, Goicoechea fails to disclose the angle of the barb as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the barb angled in the claimed range because Applicants have not disclosed that such an angle provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would be sufficient to hold the tissue and be operable in that regard. Therefore, it would have been an obvious matter of design choice to modify Goicoechea to obtain the invention as specified in the claims.

With regard to claims 92 and 93, Kanesaka fails to disclose using shape memory materials for the stent. However, Goicoechea teaches that such was known; see column 3, lines 35-63. Therefore, it is the Examiner's position that it would have been prima facie obvious to make the Kanesaka stent out of shape memory materials so that the expansion thereof could be controlled more

Art Unit: 3738

precisely and so that the use of a balloon to expand the device (an additional step) would be unnecessary.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka et al (US 5,911,754) in view of Wu et al (US 6,254,632). Kanesaka fails to disclose having grooves in the stent as claimed. However, Wu et al teaches that it was known to put grooves in stents; see the figures. Therefore, it is the Examiner's position that it would have been obvious to do the same in Kanesaka for the same reasons that Wu et al does the same.

Claims 81, 82, 95, 97, 98, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka et al (US 5,911,754) alone.

Regarding claims 81 and 82, Kanesaka fails to teach varying the strut thickness in the manner claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the strut thickness because Applicants have not disclosed that varying the strut thickness provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well when the strut thickness was not varied since manufacturing tolerances would inherently result in some strut thickness variations. Therefore, it would have been an obvious matter of design choice to modify Kanesaka to obtain the invention as specified in the claims.

With regard to claims 95 and 97, Kanesaka fails to disclose varying the number of apices as claimed. However, at the time the invention was made, it

Art Unit: 3738

would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the number of apices in order to fit smaller or larger vessels because Applicants have not disclosed that decreasing the number of apices provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well both would operate sufficiently to hold over a blood vessel. Therefore, it would have been an obvious matter of design choice to modify Kanesaka to obtain the invention as specified in the claims.

With regard to claims 98 and 101, Kanesaka fails to disclose offsetting the curvatures of the apices inner and outer sides. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to offset the curvatures of the apices because Applicants have not disclosed that doing so provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well it would not appreciably change the operation of the device. Therefore, it would have been an obvious matter of design choice to modify Kanesaka to obtain the invention as specified in the claims.

Claims 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka and Goicoechea as applied to claim 75 above, and further in view of Marin et al (US 5,397,355). Kanesaka as modified by Goicoechea fails to disclose having tuck pads and slots for the barbs as claimed.

Art Unit: 3738

However, Marin teaches that it was known to barbs with 'tuck pads' (elements (14) and (16) which hold and conceal the barb prior to delivery). Therefore, it would have been obvious to use a tuck pad with Kanesaka in order to prevent the barb from accidentally engaging the tissue or delivery device prior to deployment.

Claims 104, 105, and 116-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marin (US 5,397,355) alone.

With regard to claims 104 and 105, Marin fails to teach the claimed size range. However, the mere recitation of a size does not in itself render an unpatentable device patentable; see MPEP 2144.04

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Regarding claims 116-118, Marin fails to teach varying the strut thickness in the manner claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the strut thickness because Applicants have not disclosed that varying the strut thickness provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well when the strut thickness was not varied since manufacturing tolerances would inherently result in some

Art Unit: 3738

strut thickness variations. Therefore, it would have been an obvious matter of design choice to modify Marin to obtain the invention as specified in the claims.

With regard to claims 119 to 121, Kanesaka fails to disclose curving the ends and offsetting the curvatures of the apices inner and outer sides. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to curve and offset the curvatures of the apices because Applicants have not disclosed that doing so provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well it would not appreciably change the operation of the device. Therefore, it would have been an obvious matter of design choice to modify Marin to obtain the invention as specified in the claims.

Allowable Subject Matter

Claims 128-130 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 124-126, 131-133, 135-139, 141, and 142 are allowed over the prior art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3738

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic

Paul B. Prebilic
Primary Examiner